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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,539	03/15/2005	Karin Butz	085449-0158	3633

22428 7590 01/29/2008

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,539	BUTZ ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-62 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-62 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed October 25, 2007 in response to the Office Action of June 25, 2007, is acknowledged and has been entered. Previously pending claim 58 is amended. Claims 1-57 and 63 are canceled. Claims 58-62 and 64 are pending and are currently being examined.

Maintained Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 58-62 and 64 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection (see section 3 of the previous office Action).

The claims are drawn to a peptide which sensitizes cells for apoptosis comprising an amino acid sequence **at least 90% identical to SEQ ID NO:127** and which is capable of binding to livin-β.

The specification discloses SEQ ID NO:127 that binds to livin-β (Table 3; Examples 3-5). The specification does not disclose any other amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β as broadly encompassed in the claims.

A search of the prior and current art reveals that the art does not teach a peptide at least 90% identical to SEQ ID NO:127 and is capable of binding to livin-β, hence the art does not provide a representative number of species to support adequate written description for the broad genus of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of "amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β". Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claims do not identify which 90% of SEQ ID NO:127 must be conserved among the variants to bind to livin-β, hence the conserved structure among the claimed amino acid sequences at least 90% identical to SEQ ID NO:127 required for binding to livin-β is not adequately described.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β, per Lilly by structurally describing representative amino acid

sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β useful in the claimed invention in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses SEQ ID NO:127 that binds to livin-β, this does not provide a description of the broadly claimed amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β that would satisfy the standard set out in Enzo because the specification provides no structural features coupled to functional characteristics.

Further, the specification also fails to describe amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β by the test set out in Lilly because the specification describes only SEQ ID NO:127. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β that is required to practice the claimed invention. Since the

specification fails to adequately describe the product to which the claimed method uses, it also fails to adequately describe the method.

Response to Arguments

3. Applicants argue that a single embodiment can be more than sufficient for written description of a genus. Applicants cite *Capon v Eshhar* and *Invitrogen Corp v. Clontech Labs, Inc.* but do not point to the relevance of facts in these cases to the instant application. Applicants argue that in the present case, those of ordinary skill can readily identify every single structural variant within the claimed genus by the disclosure of the common structure, SEQ ID NO:127. Applicants argue that the remaining functional element, binding to livin-β, can be determined by no more than routine experimentation, following the examples and protocols provided by the specification. Applicants cite MPEP 2163 and state that because the determination of the functional element is routine and does not require undue experimentation, the amount of structural information that needs to be provided is correspondingly reduced (p. 4).

The arguments have been carefully considered but are not found persuasive. Neither the claims nor the specification teach the amino acids critical to the function, *i.e.*- "capable of binding to livin-β", of any amino acid sequence at least 90% identical to SEQ ID NO:127. Although the specification discloses SEQ ID NO:127 that is capable of binding to livin-β, neither the claims nor the specification teach which 90% of the amino acids are critical to the function, *i.e.*- capable of binding to livin-β, of the broad genera of amino acid sequences at least 90% identical to SEQ ID NO:127. Given the unknown

sequences required for the claimed function, one of skill in the art cannot visualize or recognize the identity of the members of the genus of amino acid sequences with 90% identity to SEQ ID NO:127 having the activity of "capable of binding to livin-β" because there is no identification of which sequences of the 90% must be conserved among the genus for the required activity, hence one of skill in the art would be subject to random screening or random experimentation to determine which of the broadly claimed peptides would function as claimed. Random experimentation is undue and is not routine.

4. Applicants state that in *Eli Lilly*, a sequence of rat insulin was disclosed but claims were drawn to human insulin. In *Eli Lilly,* providing the structure of rat insulin was insufficient to cover all proteins of the same function, regardless of structure. Applicants argue that the failure to define and claim a common structure in *Eli Lilly* is unlike the present case, in which Applicants seek to claim a genus with a shared structure, that is then further limited by a functional element (p. 4).

The arguments have been considered but are not found persuasive. In the instant claims, one of skill in the art cannot visualize or recognize the identity of the members of the genus of amino acid sequences with 90% identity to SEQ ID NO:127 having the activity of "capable of binding to livin-β" because there is no identification of which sequences of the 90% must be conserved among the genus for the required activity. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. A recitation of "at least 90%

identical to SEQ ID NO:127" encompasses a broad genus of unknown sequences and does not define the structural features commonly possessed by members of the genus that can distinguish it from others. The instant application has not identified any shared structure or required amino acids critical to the function of the activity "capable of binding to livin-β" other than SEQ ID NO:127 itself. Therefore, the specification and claims do not identify which structural features are conserved among the amino acids with 90% identity to SEQ ID NO:127, or which structures constitute a substantial portion of the genus in order for one to visualize or recognize the identity of the members of the genus, hence the written description for the broad genus of amino acid sequences at least 90% identical to SEQ ID NO:127 in the claimed methods do not meet the standards of Lilly.

5. Applicants state that in *Enzo*, the court examined the sufficiency of written description in the absence of a complete written structure, but where a functional definition was provided. Applicants state that the Federal Circuit found that this combination of partial structure and a functional definition sufficed for written description. Applicants argue that their situation is stronger than *Enzo* because a genus of complete structures are provided first and are then further limited by a functional limitation. Applicants argue that they seek to claim a limited genus that is defined according to a shared structure, and then further limit that genus by a functional limitation (p. 4-5).

The arguments have been considered but are not found persuasive because neither the claims nor the specification teach the amino acids critical to the function, *i.e.*- "capable of binding to livin-β", of any amino acid sequence at least 90% identical to SEQ ID NO:127. Although the specification discloses SEQ ID NO:127 that is capable of binding to livin-β, neither the claims nor the specification teach which 90% of the amino acids are critical to the function, *i.e.*- capable of binding to livin-β, of the broad genera of amino acid sequences at least 90% identical to SEQ ID NO:127. No genus of complete structures is provided and no shared structure is identified that would have the activity of "capable of binding to livin-β", other than SEQ ID NO:127 itself, therefore, the specification does not provide adequate written description of the broad genus of claimed peptides according to the standards of Enzo.

Claims 58-62 and 64 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record.

6. All other rejections recited in the Office Action mailed June 25, 2007 are hereby withdrawn.

7. **Conclusion:** No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER